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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/803,156	03/17/2004	Scott R. Baerson	11898.0019.DVUS02 (MOBS:0	8051

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EXAMINER	
KRUSE, DAVID H	

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 09/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/803,156	BAERSON ET AL.	
	Examiner	Art Unit	
	David H. Kruse	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 June 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,24,25 and 27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,24,25 and 27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

STATUS OF THE APPLICATION

1. This Office action is in response to the Amendment and Remarks filed 29 June 2006.

2. Those objections or rejections not specifically addressed in this Office action are withdrawn in view of Applicants' amendments.

3. The rejection under 35 U.S.C. § 102(e) as anticipated by Lebrun *et al* is withdrawn in view of Applicants amendments to the claims.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Terminal Disclaimer

5. The terminal disclaimer filed on 29 June 2006 disclaiming the terminal portion of any patent granted on this application, which would extend beyond the expiration date of U.S. Patent No. 6,803,501 B2 has been reviewed and is accepted. The terminal disclaimer has been recorded. Consequently the rejection under obviousness-type double patenting is withdrawn.

Claim Rejections - 35 USC § 101/112, first paragraph

6. 35 U.S.C. § 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claim 27 is rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a substantial asserted utility or a well-established utility.

Claim 27 is directed to an isolated DNA molecule comprising an *Eleusine* sp. gene promoter obtained by a DNA amplification method, but such a DNA molecule is

not taught in the instant application, only a method that could be used to possibly isolate such a DNA molecule. See *Brenner v. Manson*, 383 U.S. 519 (1966), which states "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point--where specific benefit exists in currently available form--there is insufficient justification for permitting an applicant to engross what may prove to be a broad field."

8. Claim 27 is also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by either a substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112

9. Claims 4, 24 and 25 remain rejected and claim 27 is rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the reasons of record in the Office action mailed 2 March 2006. Applicants' arguments filed 29 June 2006 have been fully considered but are not found to be persuasive.

New claim 27 is directed to an isolated DNA molecule comprising an *Eleusine* sp. gene promoter obtained by a DNA amplification method.

Applicants argue that they had disclosed that 5' regulatory sequences (including the promoter) is isolated from a genomic library of an *Eleusine* sp. using the disclosed nucleotide sequence of SEQ ID NO: 4 at page 61 of the specification (page 6 of the Remarks). Applicants argue that even though they did not disclose the nucleotide sequence of the 5' regulatory region, or the sequence encoding the chloroplast transit peptide, they described them in a sufficient way to convey to a person skilled in the art that Applicants were in possession (paragraph spanning pages 6-7 of the Remarks). This argument is not found to be persuasive because a description of a method that may be used to isolate a promoter sequence does not describe the isolated sequence. The Examiner also notes that the claims are not limited to sequences isolated from *E. indica*. See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. The Examiner notes that there are at least 15 recognized species in the genus *Eleusine*. See *In re Wallach*, 71 USPQ2d 1939 (CA FC 2004), at 1940: Claims in application directed to isolated DNA molecules encoding

proteins that inhibit cytotoxic effects of tumor necrosis factor were properly rejected for failure to satisfy written description requirement of 35 U.S.C. § 112, since applicants claimed nucleic acids encoding protein for which they provided only partial sequence, and without approximately 95 percent of amino acid sequence that applicants did not disclose, it cannot be held that DNA molecules claimed in application have been described, since applicants' contention that they were in physical possession of protein does not establish their knowledge of that protein's amino acid sequence or any of its other descriptive properties, even though amino acid sequence is inherent property of protein, and since application does not provide adequate functional description, in that, with only partial amino acid sequence disclosed, chemical structure of nucleic acid molecules that can serve function of encoding protein's amino acid sequence cannot be determined.

As directed to Applicant's claim of an isolated DNA that comprises the promoter region or transit peptide coding region located 5' to a DNA molecule that encodes a naturally occurring glyphosate resistant EPSPS enzyme derived from *Eleusine sp.*; See *Fiers* 25 USPQ 2d (CAFC 1993) at 1606 that states "[a]n adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it; what is required is a description of the DNA itself". See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule

sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

10. Claim 4 remains rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for an isolated DNA molecule that encodes the naturally occurring glyphosate resistant plant-derived EPSPS enzyme of SEQ ID NO: 7, wherein the glyphosate resistant EPSPS enzyme has a K_m for phosphoenolpyruvate (PEP) of less than 10μM, and wherein said naturally occurring glyphosate resistant EPSPS enzyme is modified by a substitution selected from the group consisting of glycine to alanine 102 and threonine to isoleucine 103 of SEQ ID NO:7, does not reasonably provide enablement for any isolated DNA molecule that encodes any naturally occurring glyphosate resistant *Eleusine* sp.-derived EPSPS enzyme, wherein the glyphosate resistant EPSPS enzyme has a K_m for phosphoenolpyruvate (PEP) of less than 10μM, and wherein said naturally occurring glyphosate resistant EPSPS enzyme is modified by a substitution selected from the group consisting of glycine to alanine 102 and threonine to isoleucine 103 corresponding SEQ ID NO:7. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. This rejection is repeated for the reasons of record in the Office action mailed 2 March 2006. Applicants' arguments filed 29 June 2006 have been fully considered but are not found to be persuasive.

Applicants argue that they do enable a person skilled in the art to obtain any mutant EPSPS enzyme from any *Eleusine* species by using SEQ ID NO: 6 as a probe to identify other like DNA molecules by standard methods that are routine molecular biology techniques (page 7 of the Remarks). This argument is not found to be persuasive because Applicants provide no evidence that other *Eleusine* species would produce an EPSPS enzyme that would meet the claim limitations, without also introducing other modifications to the amino acid sequence, which the Examiner views as an invitation to experiment and would, given Applicants' teachings, require undue trial and error experimentation.

Applicants argue that page 61 of the specification describes how 5' regulatory sequences can be isolated from a genomic library of an *Eleusine* sp (page 8 of the Remarks). This argument is not found to persuasive for the reasons given supra.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

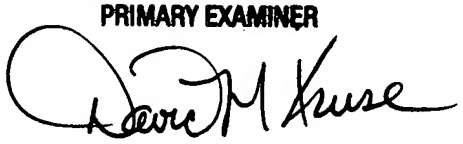
12. No claims are allowed.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at (571) 272-0975. The central FAX number for official correspondence is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-1600.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



David H. Kruse, Ph.D.
15 September 2006

14. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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